PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 10/784,066 Date: May 1, 2009

Filed: February 20, 2004 Group Art Unit: 3732

Exam: David C. Comstock

For: CLOSURE FOR ROD RECEIVING ORTHOPEDIC IMPLANT HAVING LEFT HANDED THREAD REMOVAL

- -

Kansas City, Missouri

Appeal No._____

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal in this application which was mailed on December 1, 2008.

The fees required under 41.2(b)(2) are submitted herewith.

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

The following is a related patent application on appeal to the Board of Appeals:

Serial No. 10/783,889 for which an appeal brief is being concurrently filed and with respect to which no decision has been entered.

III JURISDICTIONAL STATEMENT

This appeal is an appeal from a Patent Office action under 35 U.S.C. 134(a).

The Office action appealed from was mailed December 1, 2008. Several actions during the pendency of this application have been "Final."

The Notice of Appeal was filed December 1, 2008.

The Appeal Brief is being filed May 1, 2009 with a Request for Extension of Time until May 1, 2009 to file the Brief.

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VI STATUS OF AMENDMENTS

There are no outstanding or pending amendments.

VII GROUNDS OF REJECTION TO BE REVIEWED

1) Are Claims 1 to 20 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Shafer (DE 298 10 789 U1) in view of Jackson (6,004,349)?

VIII STATEMENT OF FACTS

Applicant is an orthopedic surgeon specializing in spinal surgery. He works daily with implanting spinal implants of the type found in the present application. He has also worked extensively with manufacturing companies that produce spinal implants both in designing entire product lines and individual implants.

Prior to the filing of the filing of the present application, Dr. Jackson recognized that there was an inherent problem with open headed bone screws of the type used in spinal surgeries. In particular, such bone screws have a receiver or head with a pair of spaced upstanding arms that form a rod receiving channel between them. The implants are quite small with a receiver that is only slightly bigger than a pencil eraser. Perhaps the most significant problem with such open

headed bone screws is that the arms are relatively small and cannot withstand much outward directed force otherwise the arms will splay or spread which can lead to catastrophic failure of the implant because an associated closure and rod become loose in the receiver after which the rod moves relative to the receiver.

One type of closure is illustrated in the Puno Patent No. 5,474,555 and provides an outer nut that goes entirely around the arms that holds the arms to keep them from splaying. However, there are several problems with the Puno nut. In particular, there is little space within which to work around the receiver along the rod. Such space is often referred to as the "run of the rod". The Puno nut significantly increases the space taken up by the bone screw along the run of the rod making it unusable in some situations. Furthermore, the nut is large and heavy. Both of these factors make the outer nut undesirable.

Other inventors, including applicant, have developed closures that slide sideways into slots in the receiver. These do not require rotation. These are hard to use in minimally invasive surgery and require a second structure for locking the rod relative to the receiver.

Other inventors have tried to use a threaded plug for the

closure that uses a conventional V-thread and is threadably received between the arms. The problem with a V-thread where the sides are, for example, at a 45° angle with respect to the base is that the torque needed to tighten the closure against the rod to lock the rod in place produces splaying of the arms. This is because the surfaces of such a thread cause approximately half of the downward force to be exerted axially and half radially outward. Because the closures must be set with a high torque for such a small device (normally about 100 inch pounds), the outward force can push the walls so as to splay them.

An inventor by the name of Metz-Stavenhagen suggested using buttress threads where, in theory, all of the forces should be exerted axially. Applicant and others, including the cited patent of Schafer (German 298 107 98) have also used reverse angle threads on the closure. Reverse angle threads should, in theory, actually pull the arms toward the closure. While buttress and reverse angle V-threads perform better than threads where the sides are both at acute angles relative to the base, all V-threads still have an inherent problem. In particular, so much force is applied and the threads are so thin that the threads can bend. As the threads are essentially smooth on both

sides, after bending, they can radially slide relative to each other which leads to splaying.

One further method has been developed to prevent splaying. This involves a closure with one or more flanges that extend radially outward and are received in similar shaped receivers in the arms. These distinguish from the closures noted above that slide in sideways in that they are rotated, twisted or screwed approximately one fourth revolution to seat in the receiver. Applicant is of the opinion that the cited Schafer reference (German 298 10 798) also shows such a structure which will be discussed more extensively in the argument's section. There are a number of problems with such devices. In particular, such closures must be pushed down against the rod until the flanges on the closure align with the flange receivers on the arms and then rotated until joined which typically requires a 90° rotation of the closure. During assembly, the closure of such devices can not be advanced in a helically wound path under the guidance of the receiver, so such are difficult to install and typically another device such as a set screw must be used to lock the rod.

Applicant has developed a closure with a radially interlocking structure between the closure and the arms of the

receiver that resists splaying of the arms even at a high setting torque and that requires no other structure such as a set screw to lock the rod in place. The high torque ensures that the rod will not slip or move relative to the receiver which can seriously compromise the value of the implant and could cripple the patient.

IX ARGUMENT

The pending claims were rejected as obvious in view of a combination of Schafer (German 298 10 798 - previously noted) and Jackson (6,004,349).

The cited Schafer patent is directed to two different embodiments. The first embodiment is a closure of the type with a reverse angle thread, as previously discussed and as is shown in Fig. 1 of Schafer. The reverse angle thread of Fig. 1 is a V-thread with smooth sides which can bend and radially slide relative to one another and is urged to not in any way show or describe the radially interlocking structures between the closure body and arms as is called for in applicant's claims.

The second embodiment of Schafer is shown in Fig. 2. This embodiment was apparently added as a quick after thought and

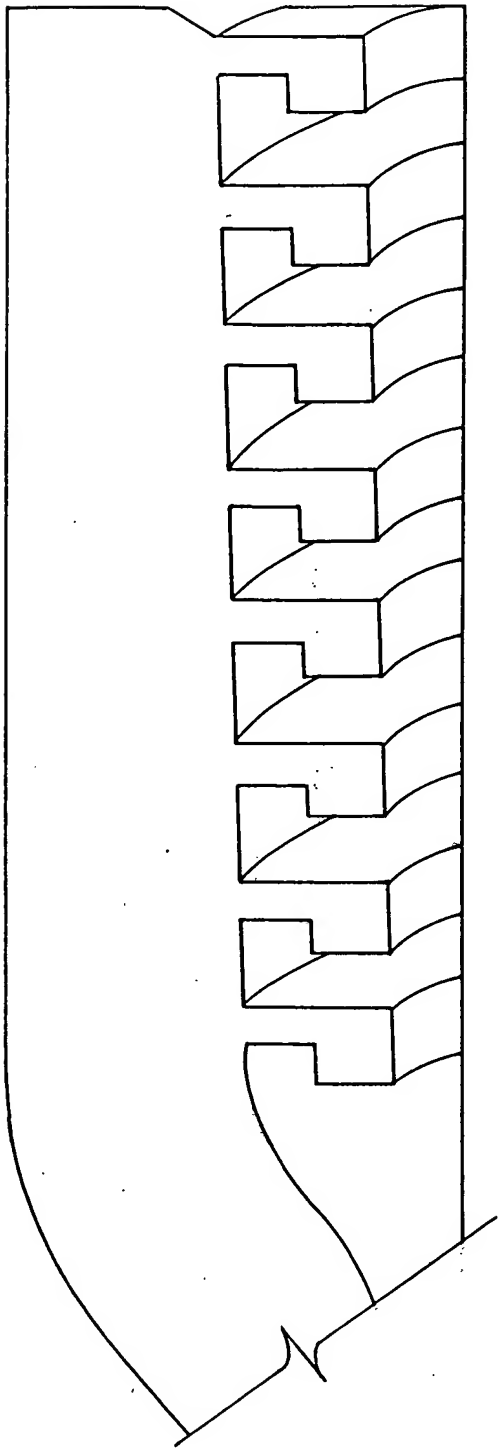
includes only a partial cross section of the receiver in Fig. 2 and a single paragraph describing the embodiment of Fig. 2. The last Office Action cites the paragraph describing Fig. 2 as follows.

> In the exemplary embodiment shown in Figure 2, the bifurcated head 4 of the bone screw 1 likewise has a **thread**, which, however, has a top flank 11 and a bottom flank 10 embodied in a stepped fashion. The should of the bottom flank 10 is shaped such that it forms an undercut 17. This undercut 17, particularly by means of the should 18, prevents the legs 5 from being bent radially outward while the **grub screw** 3 is being **screwed in**. A positive lock is thus produced in the radial direction between the bifurcated head 4 and grub screw 3. This positive lock prevents, as previously mentioned, any slippage of the leg 5. (Emphasis added by the Office action).

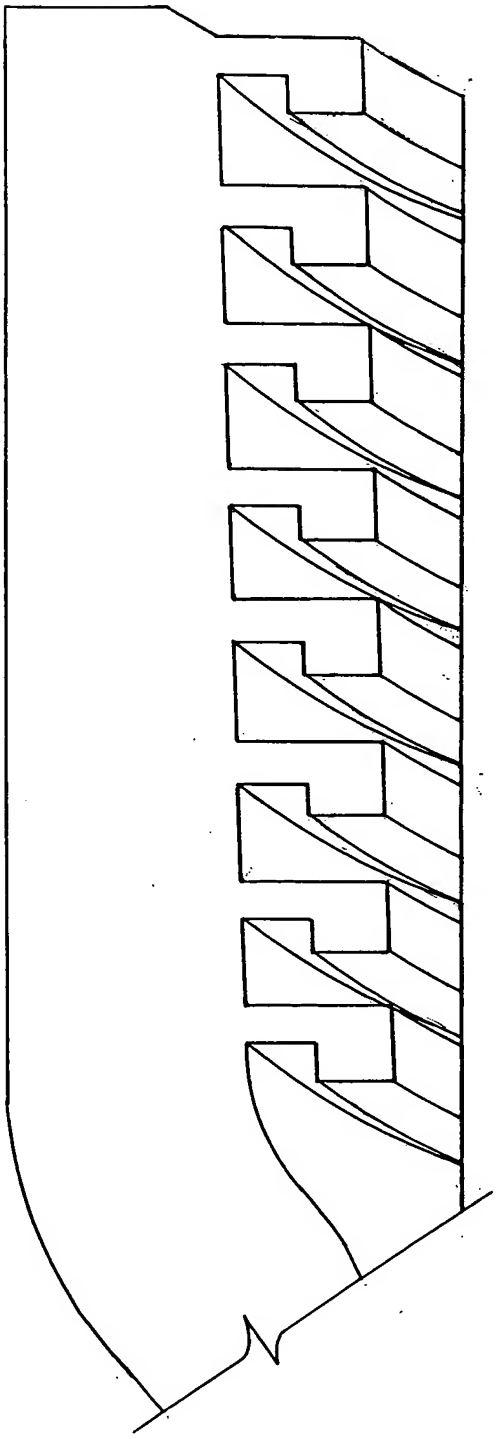
The Office action argues that this paragraph and Fig. 2 clearly show and describe a helically wound structure of the type claimed by applicant. Applicant respectfully disagrees.

In particular, one must take the disclosure of Schafer in

light of what was known to one having ordinary skill in the art at the priority date of the present application. The art of this invention is quite complex, but no one had previously shown an interlocking structure that was helically wound. When reviewing the Schafer patent, as one having skill in the art at the priority date would have done, an engineer or other skilled person would look to see what Schafer actually teaches. Schafer neither shows or teaches a closure, so a closure must be somehow imagined to work with the receiver of Fig. 2. In studying that receiver to see how to make a closure, it is clear that all of the tiers of structure (seven complete in total) are equally spaced from the bottom of the channel on both the front and back sides of each tier, as shown in the drawing. Consequently, it is impossible for the tiers to have a pitch and, likewise, it is impossible for such tiers to be helically wound. On the following page is a representation on the left that is Fig. 2 of the Schafer reference and a representation on the right that is of a structure modified with respect to Schafer, if Schafer were to be helically wound.



SCHAFER
FIG. 2



SCHAFER MODIFIED TO BE HELICALLY WOUND CONSISTENT WITH APPLICANT'S INVENTION

It is apparent from reviewing these two images that one having skill in the art would immediately see that the device of Fig. 2 of Schafer is not helically wound and was of the type of closure described in the Statement of Facts section wherein the mating structure on the closure was not helically wound, but rather the closure and receiver were aligned and the closure twisted or rotated 90° to secure them together.

The geometry of applicant's device is quite complex because a compound and complicated surface is being helically wound about the closure and a like structure is being wound about the inside of the arms. It is urged that at the time of filing, it was not apparent to one having skill in the art that such a complex structure could be made or that it could work upon rotation during assembly. Perhaps even more important is that the Schafer structure does not suggest to one having ordinary skill in the art should even look at or try to make a helically wound device. It is noted that machine shops were unable to manufacture applicant's device for many years because of the great complexity, even after applicant told them what he wanted. The Office action points out that the short disclosure in Schafer indicates that there is a thread and that a grub screw is screwed

into it. A closure of the type described above that was not helically wound and had structure that mated upon rotating 90° can be called a grub screw and rotation or twisting can be interpreted as being "screwed in" to distinguish from the closures that are slid in sideways without rotating. Consequently, it is believed that applicant's interpretation of Schafer is completely consistent with the written description, especially as it would be interpreted by one with skill in the art at the time. The drawing of Schafer would either teach one to make a non helically wound device or, alternatively, fails to teach how to make any effective device.

It is further noted that Schafer was a well known German inventor who had many U.S. patents. It is interesting to review these patents because of what his later patents show. Schafer's 289 10 798 German patent has publication and other dates in the late 1990's. Nevertheless, when he designed later closures, he used the "align and twist 90°" structure that is urged to be shown in the earlier patent rather than a helical wound structure. For example, the following views are from his US 6,340,749 patent that was filed in 2002.

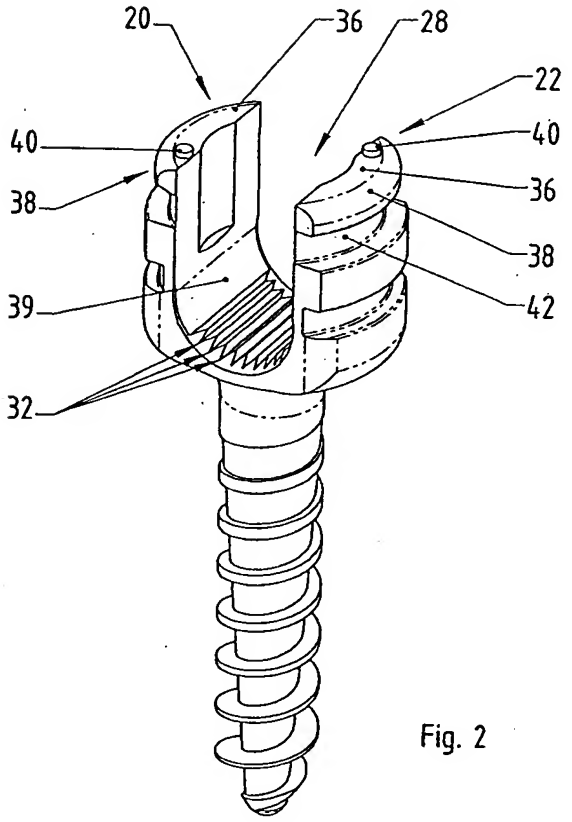


Fig. 2

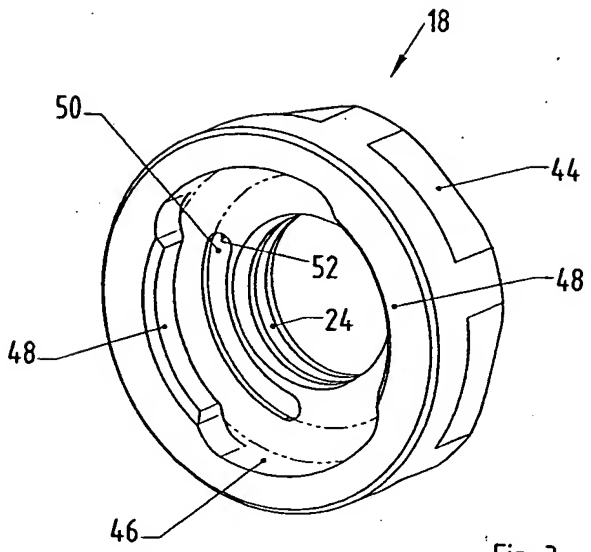


Fig. 3

The structure shown in the 6,540,749 patent clearly has an "align and twist 90°" closure (nut 18) that mates with a receiver (head 16) having receiving structure. If Schafer had conceived

of the helically wound structure earlier, why did he use the "align and twist" structure rather than the preferable helically wound structure that does not require an additional locking screw (26)? The answer is that Schafer had not envisioned such technology and that anyone of ordinary skill in the art who reviewed Schafer's patent, also would not envision such technology based upon his teachings. Persons trying to better understand the poorly presented Schafer reference that was cited might look to his later patents and see the "align and twist" type closure, as noted in Patent No. 6,540,749. It is noted that applicant's prior patent 6,004,349 is cited as satisfying the claim requirement of a left handed thread having a plurality of complete revolutions. The earlier Jackson patent was directed to a set screw (not a closure) that had a conventional V-thread and that was designed for being received in a fully surrounding bore. The set screw was not heavily torqued and because of this could be removed with an easy out provided a starter thread of about one half revolution was provided. Applicant's current invention is to a closure between arms that is heavily torqued to give a good solid seat. The removal structure for this closure is a left handed thread of multiple revolutions that mates with a

similar removal tool. Because of the high setting torque, the simple partial revolution thread taught in applicant's prior patent is insufficient and multiple revolutions are required. It is urged that applicant's invention further distinguishes from the cited prior art for this reason, as the cited prior art fails to teach one of skill in the art to use the stronger multiple revolution thread with a different tool to allow for removal. Consequently, it is urged that a combination of Schafer and Jackson fails to make obvious the pending claims for the noted reasons. It is also urged that Schafer fails to in anyway suggest or teach applicant's claimed invention to one having ordinary skill in the art whether taken alone or in combination with the cited Jackson reference.

X CLAIMS APPENDIX

A. PENDING CLAIMS

Claim 1 A closure for setting engagement with a structural member and comprising:

(a) a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis;

(b) a guide and advancement flange extending helically about said outer cylindrical surface and having a forward advancement direction relative to said closure axis, said flange having a leading surface and a trailing surface relative to said forward advancement direction;

(c) at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component facing generally toward said closure axis;

(d) a driving structure for rotating and torquing said body to a preselected torque; and

(e) said body having an axially aligned bore opening on a trailing surface of said body; said bore having a left handed thread that includes a plurality of complete

revolutions of the thread about the bore therein that is sized and shaped to be adapted to receive a removal tool with a mating left handed thread for removing said body subsequent to installation.

Claim 2 The closure as set forth in Claim 1 wherein said bore is exposed by removal of said driving structure.

Claim 3 (Original) The closure as set forth in Claim 1 wherein:

(a) said apertures extend from said body trailing surface partially therethrough.

Claim 4 The closure as set forth in Claim 1 wherein:

(a) said driving structure is an installation head that includes a grippable radially outer surface that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level of torque between said installation head and said

closure to enable separation of said installation head from said closure.

Claim 5 The closure as set forth in Claim 1 and including:

(a) said closure having a leading surface relative to said forward advancement direction; and

(b) said body having a V-shaped set ring and an axially aligned point formed on said leading end to enhance setting engagement of said closure into a surface of a structural member.

Claim 6 The closure as set forth in Claim 1 in combination with a bone implant screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implanting into a bone;

(b) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel therebetween to receive a bone fixation structural member; and

(c) said mutually facing channel surfaces each having

mating guide and advancement structure formed therein which are compatible for mating with said guide and advancement flange of said closure to enable rotation guiding and advancement of said closure into said channel so as to be adapted to clamp said bone fixation structural member when positioned therein.

Claim 7 The closure and bone implant screw combination as set forth in Claim 6 wherein:

(a) said mating guide and advancement structure of said bone implant screw include an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure to provide an interlocking fit when joined so as to resist splaying of said arms in reaction to forces applied thereto.

Claim 8 The closure and bone screw combination as set forth in Claim 7 wherein:

(a) said guide and advancement flange has a relatively enlarged outer periphery which forms said inward anti-

splay surface component;

(b) said mating guide and advancement structures are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw.

Claim 9 A closure for setting engagement with a structural member and comprising:

(a) a body having an outer cylindrical surface relative to a central closure axis and a driving installation head;

(b) a guide and advancement flange extending helically and substantially continuously about said outer cylindrical surface and having a forward advancement direction relative to said closure axis, said flange having a trailing surface relative to said forward advancement direction;

(c) said trailing surface being compound in contour and

including an inward anti-splay surface component facing generally toward said closure axis; and

(d) said body having an axially aligned bore formed therein that opens onto a trailing surface of said body; said bore having a helically wound left handed thread therein that extends a plurality of revolutions about the bore; said bore thread being sized and shaped to receive a removal tool having a mating left handed thread.

Claim 10 The closure as set forth in Claim 9 including:

(a) an installation head that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level of torque between said installation head and said closure to enable separation of said installation head from said closure.

Claim 11 The closure as set forth in Claim 9 and including:

(a) said closure having a leading end relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring and an axially aligned point formed on said leading end to enhance setting engagement of said closure into a surface of a structural member.

Claim 12 The closure as set forth in Claim 9 in combination with a bone implant screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implanting into a bone;

(b) an open head having a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member therebetween; and

(c) each of said mutually facing channel surfaces having mating internal guide and advancement structure formed therein which are compatible with said flange of said closure to enable advancement of said closure into said

channel to thereby clamp said bone fixation structural member when positioned therein.

Claim 13 The closure and bone implant screw combination as set forth in Claim 12 wherein:

(a) each of said guide and advancement structures of said bone implant screw include an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure in such a manner as to resist a tendency of said arms to splay in reaction to torquing said closure into engagement with said fixation structural member.

Claim 14 The combination as set forth in Claim 13 wherein:

(a) said flange has a relatively enlarged outer periphery which forms said inward anti-splay surface component;

(b) each of said guide and advancement structures are contoured in a complementary manner to said external thread to form said outward anti-splay surface component; and

(c) said inward anti-splay surface component engages said

outward anti-splay surface component when said closure is rotated into said open screw head of said bone implant screw.

Claim 15 A closure for setting engagement with a structural member and including a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis and a substantially continuous guide and advancement flange extending helically about said outer cylindrical surface and having a forward advancement direction relative to said screw axis; said flange having a leading surface and a trailing surface relative to said forward advancement direction; at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component facing generally toward said closure axis; and said body having an axially aligned bore that opens onto a trailing surface of said body; said bore having a left handed helically wound thread that extends a plurality of revolutions around the bore sized and shaped to mate with a removal tool having a mating left handed thread.

Claim 16 The closure as set forth in Claim 15 wherein said bore extends from said trailing surface of said body only partially through said body.

Claim 17 The closure as set forth in Claim 15 and including:

(a) an installation head that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level of torque between said installation head and said closure to enable separation of said installation head from said closure.

Claim 18 The closure as set forth in Claim 15 wherein:

(a) said closure has a leading end relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring and a point formed on said forward end to enhance setting engagement of said closure into a surface of such a

structural member.

Claim 19 The closure as set forth in Claim 15 in combination with a bone screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implantation into a bone;

(b) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member;

(c) each of said mutually facing channel surfaces having respective mating guide and advancement structures formed therein which are compatible with said guide and advancement flange of said closure to enable guiding and advancement of said closure into said channel to thereby clamp said bone fixation structural member therein; and

(d) said mating guide and advancement structures of said bone implant screw including an outward anti-splay surface component which cooperates with said inward

anti-splay surface component of said closure in such a manner as to resist a tendency of said arms to splay in reaction to forces being applied thereto.

Claim 20 The closure and bone screw combination as set forth in Claim 19 wherein:

(a) said guide and advancement flange has a relatively enlarged outer periphery region which forms said inward anti-splay surface component;

(b) said mating guide and advancement structures are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw.

B. CLAIM SUPPORT AND DRAWING ANALYSIS

Claim 1 A closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and see Figs. 1-9} and comprising:

(a) a substantially cylindrical body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25,page 29, lines 1-2};

(b) a guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically about said outer cylindrical surface and having a forward advancement direction relative to said closure axis {see Figs. 1-2}, said flange having a leading surface {27, page 29, lines 1-4, and see Fig. 2} and a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to said forward advancement direction;

(c) at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30, lines 6-19} facing generally toward said closure axis;

(d) a driving structure {6, page 28, lines 6-8, and page 29, line 4 to page 30, line 3} for rotating and torquing said body to a preselected torque; and

(e) said body having an axially aligned bore {2, page 28, lines 5-6, and page 32, lines 18-21, and see Figs. 3, 5, 8 and 9} opening on a trailing surface of said body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; said bore having a left handed thread {47, page 32, lines 19-21} that includes a plurality of complete revolutions of the thread about the bore {see Figs. 5 and 9} therein that is sized and shaped to be adapted to receive a removal tool {50, page 33, lines 3-14} with a mating left handed thread {55, page 33, lines 5-7} for removing said body subsequent to installation {page 33, lines 13-14}.

Claim 2 The closure as set forth in Claim 1 wherein said bore {2, page 18, line 18 to page 33, line 2, and see Fig. 7} is exposed by removal of said driving structure {6, page 18, line 18 to page 33, line 2, and see Fig. 7}.

Claim 3 The closure as set forth in Claim 1 wherein:

(a) said apertures extend from said body trailing surface partially therethrough.

Claim 4 The closure as set forth in Claim 1 wherein:

(a) said driving structure is an installation head {6, page 29, lines 13-15} that includes a grippable radially outer surface {31, page 29, lines 13-15} that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region {30, page 29, lines 4-13} formed in such a manner that said breakaway region fails in response to a selected level of torque {page 29, lines 4-13} between said installation head and said closure to enable separation of said installation head from said closure.

Claim 5 The closure as set forth in Claim 1 and including:

(a) said closure having a leading surface {27, page 29, lines 1-4, and see Figs. 2, 4, 5-7 and 9} relative to

said forward advancement direction; and

(b) said body having a V-shaped set ring {42, page 31, lines 9-19, and see Figs. 4-5} and an axially aligned point {43, page 31, lines 9-19, and see Figs. 4-5} formed on said leading end to enhance setting engagement of said closure into a surface of a structural member {10, page 31, lines 9-19} .

Claim 6 The closure as set forth in Claim 1 in combination with a bone implant screw {8, page 28, lines 8-23 and page 30, line 4 to page 31, line 8} adapted for connection to a bone fixation structural member {10, page 28, lines 8-23 and page 30, line 4 to page 31, line 8}, said bone implant screw including:

(a) a threaded shank {14, page 28, lines 13-14} adapted for threaded implanting into a bone {12, page 28, lines 13-14};

(b) an open head {16, page 28, lines 13-15} formed by a pair of spaced apart arms {18, page 28, lines 15-17} having mutually facing channel surfaces defining a structural member receiving channel {20, page 28, lines 16-17} therebetween to receive a bone fixation

structural member {10, page 28, lines 16-17}; and

(c) said mutually facing channel surfaces each having mating guide and advancement structure {22, page 28, lines 17-19 and page 30, lines 8-13} formed therein which are compatible for mating with said guide and advancement flange {35, page 30, lines 4-19} of said closure to enable rotation guiding and advancement of said closure into said channel {page 31, lines 5-8} so as to be adapted to clamp said bone fixation structural member when positioned therein {page 30, lines 4-19, page 31, lines 5-8}.

Claim 7 The closure and bone implant screw combination as set forth in Claim 6 wherein:

(a) said mating guide and advancement structure {22, page 28, lines 17-19 and page 30, lines 8-13} of said bone implant screw include an outward anti-splay surface component {39, page 30, lines 8-19, and see Fig. 9} which cooperates with said inward anti-splay surface component {37, page 30, lines 6-19, and see Fig. 9} of said closure to provide an interlocking fit {page 30,

lines 13-19, and see Fig. 9} when joined so as to resist splaying of said arms in reaction to forces applied thereto.

Claim 8 The closure and bone screw combination as set forth in Claim 7 wherein:

(a) said guide and advancement flange {35, page 30, lines 6-8, and see Figs. 5 and 9} has a relatively enlarged outer periphery which forms said inward anti-splay surface component {37, page 30, lines 6-8, and see Figs. 5 and 9};

(b) said mating guide and advancement structures {22, page 30, lines 8-13} are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component {39, page 30, lines 8-13}; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw {page 30, lines 13-19, and page 31, lines 5-8}.

Claim 9 A closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and see Figs. 1-9} and comprising:

(a) a body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25, page 29, lines 1-2} and a driving installation head {6, page 28, lines 6-7};

(b) a guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically and substantially continuously about said outer cylindrical surface and having a forward advancement direction relative to said closure axis {see Figs. 1-2}, said flange having a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to said forward advancement direction;

(c) said trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30, lines 6-19} facing generally toward said closure axis; and

(d) said body having an axially aligned bore {2, page 28,

lines 6-8, and page 29, line 4 to page 30, line 3} formed therein that opens onto a trailing surface of said body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; said bore having a helically wound left handed thread {47, page 32, lines 19-21} therein that extends a plurality of revolutions about the bore {see Figs. 5 and 9}; said bore thread being sized and shaped to receive a removal tool {50, page 33, lines 3-14} having a mating left handed thread {55, page 33, lines 5-7}.

Claim 10 The closure as set forth in Claim 9 including:

(a) an installation head {6, page 29, lines 13-15} that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region {30, page 29, lines 4-13} formed in such a manner that said breakaway region fails in response to a selected level of torque {page 29, lines 4-13} between said installation head and said closure to enable separation of said installation head from

said closure.

Claim 11 The closure as set forth in Claim 9 and including:

(a) said closure having a leading end {27, page 29, lines 1-4, and see Figs. 2, 4, 5-7 and 9} relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring {42, page 31, lines 9-19, and see Figs. 4-5} and an axially aligned point {43, page 31, lines 9-19, and see Figs. 4-5} formed on said leading end to enhance setting engagement of said closure into a surface of a structural member {10, page 31, lines 9-19}.

Claim 12 The closure as set forth in Claim 9 in combination with a bone implant screw {8, page 28, lines 8-23, and page 30,, lines 4 to page 31, line 8} adapted for connection to a bone fixation structural member {10, page 28, lines 8-23 and page 30, line 4 to page 31, line 8}, said bone implant screw including:

(a) a threaded shank {14, page 28, lines 13-14} adapted for threaded implanting into a bone {12, page 28, lines 13-14};

(b) an open head {16, page 28, lines 13-15} having a pair of spaced apart arms {18, page 28, lines 15-17} having mutually facing channel surfaces defining a structural member receiving channel {20, page 28, lines 16-17} to receive a bone fixation structural member {10, page 28, lines 16-17} therebetween; and

(c) each of said mutually facing channel surfaces having mating internal guide and advancement structure {22, page 28, lines 17-19 and page 30, lines 8-13} formed therein which are compatible with said flange {35, page 30, lines 4-19} of said closure to enable advancement of said closure into said channel to thereby clamp said bone fixation structural member when positioned therein {page 30, lines 4-19, and page 31, lines 5-8}.

Claim 13 The closure and bone implant screw combination as set forth in Claim 12 wherein:

(a) each of said guide and advancement structures {22, page 28, lines 17-19 and page 30, liens 8-13} of said bone implant screw include an outward anti-splay surface component {39, page 30, lines 8-19, and see Fig. 9}

which cooperates with said inward anti-splay surface component {37, page 30, lines 6-19, and see Fig. 9} of said closure in such a manner as to resist a tendency of said arms to splay in reaction to torquing said closure into engagement with said fixation structural member {page 30, lines 13-19}.

Claim 14 The combination as set forth in Claim 13 wherein:

(a) said flange {35, page 30, lines 6-8, and see Figs. 5 and 9} has a relatively enlarged outer periphery which forms said inward anti-splay surface component {37, page 30, lines 6-8, and see Figs. 5 and 9};

(b) each of said guide and advancement structures are contoured in a complementary manner to said external thread to form said outward anti-splay surface component {39, page 30, lines 8-13}; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is rotated into said open screw head of said bone implant screw {page 30, lines 13-19, and page 31, lines 5-8}.

Claim 15 A closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and se Figs. 1-9} and including a substantially cylindrical body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25, page 29, lines 1-2} and a substantially continuous guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically about said outer cylindrical surface and having a forward advancement direction relative to said screw axis {see Figs. 1-2}; said flange having a leading surface {27, page 29, lines 1-4, and see Fig. 2} and a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to said forward advancement direction; at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30, lines 6-19} facing generally toward said closure axis; and said body having an axially aligned bore {2, page 28, lines 5-6, and page 32, lines 18-21, and see Figs. 3, 5, 8 and 9} that opens onto a trailing surface of said body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; said bore having a left handed

helically wound thread {47, page 32, lines 19-21} that extends a plurality of revolutions around the bore {see Figs. 5 and 9} sized and shaped to mate with a removal tool {50, page 33, lines 3-14} having a mating left handed thread.

Claim 16 The closure as set forth in Claim 15 wherein said bore extends from said trailing surface of said body only partially through said body {page 28, lines 5-6}.

Claim 17 The closure as set forth in Claim 15 and including:

(a) an installation head {6, page 29, lines 13-25} that is shaped to enable non-slip engagement of said installation head by an installation tool {page 29, lines 13-15}; and

(b) said installation head being connected to said closure by a breakaway region {30, page 29, lines 4-13} formed in such a manner that said breakaway region fails in response to a selected level of torque {page 29, lines 4-13} between said installation head and said closure to enable separation of said installation head from said closure.

Claim 18 The closure as set forth in Claim 15 wherein:

(a) said closure has a leading end {27, page 29, lines 1-4} relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring {42, page 31, lines 9-19} and a point {43, page 31, lines 9-19} formed on said forward end to enhance setting engagement of said closure into a surface of such a structural member {10, page 31, lines 9-19}.

Claim 19 The closure as set forth in Claim 15 in combination with a bone screw {8, page 28, lines 8-23, and page 30, line 4 to page 31, line 8} adapted for connection to a bone fixation structural member {10, page 28, lines 8-23, and page 30, line 4 to page 31, line 8}, said bone implant screw including:

(a) a threaded shank {14, page 28, lines 13-14} adapted for threaded implantation into a bone {12, page 28, lines 12-14};

(b) an open head {16, page 28, lines 13-15} formed by a pair of spaced apart arms {18, page 28, lines 15-17} having mutually facing channel surfaces defining a structural member receiving channel {20, page 28, lines

16-17} to receive a bone fixation structural member {10, page 28, lines 16-17};

(c) each of said mutually facing channel surfaces having respective mating guide and advancement structures {22, page 28, lines 17-19, and page 30, lines 8-13} formed therein which are compatible with said guide and advancement flange {35, page 30, lines 4-19} of said closure to enable guiding and advancement of said closure into said channel {page 31, lines 5-8} to thereby clamp said bone fixation structural member therein {page 30, lines 4-19, and page 31, lines 5-8}; and

(d) said mating guide and advancement structures {22, page 28, lines 17-19 and page 30, lines 8-13} of said bone implant screw including an outward anti-splay surface component {39, page 30, lines 8-19, and see Fig. 9} which cooperates with said inward anti-splay surface component {37, page 30, lines 6-19, and see Fig. 9} of said closure in such a manner as to resist a tendency of said arms to splay in reaction to forces being applied thereto {page 30, lines 13-19, and page 31,

lines 5-8}.

Claim 20 The closure and bone screw combination as set forth in Claim 19 wherein:

(a) said guide and advancement flange {35, page 30, lines 6-8, and see Figs. 5 and 9} has a relatively enlarged outer periphery region which forms said inward anti-splay surface component {37, page 30, lines 6-8, and see Figs. 5 and 9};

(b) said mating guide and advancement structures {22, page 30, lines 8-13} are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component {39, page 30, lines 8-13}; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw {page 30, lines 13-19, and page 31, lines 5-8}.

C. EVIDENCE APPENDIX

NONE

D. RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

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